DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

Certified/Return Receipt Requested

February 11, 1999

WARNING LETTER

James C. Lane, Chief Executive Officer
LSI International, Inc.
8849 Bond
Overland Park, KS 66214

KAN #99-012

Dear Mr. Lane:

We are writing to you because on December 16 through 31, 1998, an FDA Investigator from this office conducted an inspection at your facility located at the above address, which revealed a serious regulatory problem involving your electronic muscle stimulator and interferential therapy devices.

Under the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices. The law requires that manufacturers of medical devices adhere to the Quality System Regulations. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to maintain complete documentation for complaints received regarding your medical device products.

- Failure to establish rework procedures for nonconforming products, which would include retesting and re-evaluation after rework.

- Failure to have procedures in place for implementing and reviewing corrective and preventive actions.

- Failure to document management with executive responsibility, and to establish a quality policy with objectives to ensure the quality system requirements are met.

- Failure to establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured.

- Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

- Failure to have all your procedures in your Quality Audit Procedures Log signed and dated by the individual approving the documents.

This letter is not intended to be an all-inclusive list of deficiencies at your Kansas City, Kansas, facility. At the conclusion of the inspection Form FDA 483 was issued to and discussed with you.. This is a list of the QSR deviations made by the Investigator during the inspection.

It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your

correction. Please direct your response to Clarence R. Pendleton, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the content of this letter, please feel free to contact Mr. Clarence R. Pendleton at (913) 752-2103.

Sincerely,

Barbara Glasier
for

W. Michael Rogers
District Director
Kansas City District